

## **REMARKS**

Claim 1 has been amended and claim 18 has been cancelled without prejudice or disclaimer. Claims 1, 3-6, and 8-17 are pending in the instant application. No new matter has been added as a result of the above-described amendments. The objections and rejections set forth in the Office Action have been overcome by amendment.

### **1. Rejection of claims 1, 3-6, and 8-18 under 35 U.S.C. § 112, first paragraph**

The Office Action asserts a rejection of claims 1, 3-6, and 8-18 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. In particular, the Action asserts that the specification, while being enabling for a method of isolating cells having stem cell-like characteristics of SSEA-4 and Tra-1-60 marker expression, from human milk, and cells isolated by said method, does not reasonably provide enablement for a method of isolating pluripotent progenitor cells from any human mammary secretions of a male or female, or pluripotent progenitor cells isolated from any human mammary secretion, as broadly claimed. The Action states that the disclosure is an invitation to a person of ordinary skill in the art to engage in further experimentation to discover whether the SSEA-4 and Tra-1-60 positive cells isolated from human milk are capable of differentiating into any of the claimed cell types, and whether such cells may be isolated from any type of mammary secretion from a male or female. The Action also states that the presence of SSEA-4 and Tra-1-60 markers on the surface of a cell is not sufficient to show pluripotency of the cell (Badcock *et al.*, 1999, *Cancer Res.* 59: 4715-19; U.S. Patent Application Publication No. 2005/0095708). The Action concludes that in view of the art recognized high level of unpredictability regarding the pluripotency of a cell based on the presence of two cell surface markers, and the teachings of the prior art, together with the large quantity of research required to define these unpredictable variables, and the lack of guidance provided in the specification regarding the same, it would require undue experimentation for one of ordinary skill in the art to practice the scope of the claimed invention.

In an effort to expedite prosecution of the pending claims to allowance, and in view of the Action's acknowledgement that the specification is enabling for a method of isolating cells having

stem cell-like characteristics of SSEA-4 and Tra-1-60 marker expression, Applicants have amended claim 1 to recite a method for isolating pluripotent progenitor cells having stem cell-like characteristics of SSEA-4 and Tra-1-60 marker expression from a human mammary secretion of a male or female human body. Applicants reserve the right to pursue claims directed to methods for isolating pluripotent progenitor cells having stem cell-like characteristics from a human mammary secretion of a male or female human body in a timely filed continuation or divisional application, or alternatively, reintroduce such subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance. Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

## **2. Rejection of claim 18 under 35 U.S.C. § 102**

The Office Action asserts a rejection of claim 18 under 35 U.S.C. § 102(b) as being anticipated by Draper *et al.*, 2002, *Curr. Opinion Obstet. Gynecol.* 14: 309-15. The Action states that Draper *et al.* teach human pluripotent stem cells capable of differentiating into all of the cell types present in the adult body, as well as human embryonic stem cells that display immunoreactivity with SSEA-4 and Tra-1-60. The Action also states that in the absence of factual evidence to the contrary, the burden is upon Applicants to establish patentable differences between the claimed pluripotent progenitor cells and those taught in the prior art.

In an effort to expedite prosecution of the pending claims to allowance, Applicants have cancelled claim 18. Applicants reserve the right to pursue claims directed to the cancelled subject matter in a timely filed continuation or divisional application, or alternatively, reintroduce the cancelled subject matter in the instant application at such time as the Office indicates that the pending claims are otherwise in condition for allowance. Applicants respectfully request that the rejection under 35 U.S.C. § 102 be reconsidered and withdrawn.

## **CONCLUSIONS**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Sajjadi believes it to be helpful, he is invited to contact the undersigned

representative by telephone at 312-913-0001.

Respectfully submitted,  
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